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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/632,810 | 08/04/2003 | Atsushi Suzuki | 241113US0DIV | 4609 |
| 22850 7590 06/01/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER UNDERDAHL, THANE E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
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| | | | 06/01/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/632,810 | | SUZUKI ET AL. | |
| | Examiner | | Art Unit | |
| | Thane Underdahl | | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 20-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 20-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/022,694.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Action Summary

This office action is responsive to applicants remarks filed 2/26/07.

Claims 1-10, 14-19 have been cancelled. Claims 11-13 and new claims 20-38 are pending in this action.

Response to Applicant's Arguments— 35 U.S.C § 112

In response to the applicants argument against the rejection of claims 3, 4, 5, 12, 13 and 19. This rejection is dropped in view of Applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 102

In response to the applicants argument against the rejection of claims 1-6 and 8. This rejection is dropped since Applicant cancelled these claims.

Response to Applicant's Arguments— 35 U.S.C § 103

Response to Applicants Amendment

In the response submitted by the applicant on [Date] , the 35 U.S.C § 103 (a) or rejection of claims 11-19 over Abraham in view of Hsu (U.S. Patent # 5,958,417) as supported by McGraw-Hill ("hypertension." McGraw-Hill Encyclopedia of Science and Technology) and Yokozawa et al. (Phytotherapy Research, 1995) were considered but not found persuasive.

The Applicant argues that while Abraham teach a composition of ferulic acid, caffeic acid, and chlorogenic acid is added to coffee that he does not teach the composition is administered to treat hypertension. The applicant further argues the additional teachings of Hsu and Yokozawa et al. do no motivate the application of the Abraham's composition to treat hypertension since Hsu and Yokozawa only teach that chlorogenic acid and caffeic acid are useful for treating hypertension.

However, the examiner points out that since Yokozawa and Hsu teach the addition of chlorogenic and caffeic acid to the diet controls hypertension. It would be obvious to one of ordinary skill in the art to use the composition of Abraham in this capacity since it contains substantial amounts of these anti-hypertensives. The Applicant argues, "there is no such motivation to add ferulic acid to this composition and to expect the same result". However since the composition of Abraham has at least two identifiable anti-hypertensives as taught by Yokozawa and Hsu and Abraham has shown that their compositions is edible, the motivation is present to apply the composition of Abraham to treat hypertension. As for the reasonable expectation of success, Yokozawa (page 107, table 1) and Hsu (Crataegus, Figure 1) show that these compounds do treat hypertension so there is a ground for reasonable expectation of success. So it would be obvious to use the composition of Abraham that contains ferulic acid, caffeic acid, and chlorogenic acid to treat hypertension with the motivation and reasonable expectation of success provided by Yokozawa and Hsu.

The Applicant argues that no motivation exists to add ferulic acid a composition of caffeic acid and chlorogenic acid. However such a composition has already been taught by Abraham and no motivation is required to add the three acids together in a composition. The Examiner believes that the question of argument is if there is motivation to use Abraham's composition to treat hypertension has been affirmatively answered by Yokozawa and Hsu above.

That Applicant continues to argue that the method of treating hypertension is obvious because of there are "clear advantages of co-administration of ferulic acid with

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caffeic acid and/or chlorogenic acid". The Applicant directs the Examiner's attention to Table 1 of the specification. The Applicant claims that the results of Test Plots 4-6 show a synergistic effect of co-combining these acids. However, one of ordinary skill in the art would recognize that to show synergism the effect of the two components must be *greater* than the sum of their individual effects. This is not the case shown in the data in table 1. When accounting for the error, the effects of the various compositions of ferulic, caffeic and chlorogenic acids on the systolic blood pressure are simply the sum of their individual effects. For example, the mean values of Ferulic acid (-7.8), added to the mean values of Caffeic acid (-4.1) or Chlorogenic acid (-3.2) are -11.9 and -11 respectively which are within the experimental results of their combination shown in Table 1. Therefore synergistic effects are not present.

Therefore the rejection stands and is repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-19 remain rejected and new claims 20-38 are rejected under 35 U.S.C.

103(a) as being unpatentable over Abraham as applied above in view of Hsu (U.S.

Patent # 5,958,417) as supported by McGraw-Hill ("hypertension." McGraw-Hill

Encyclopedia of Science and Technology) and Yokozawa et al. (Phytotherapy Research, 1995).

These claims are drawn to a method of treatment for hypertension or high blood pressure and also for reducing a rise in blood pressure using compositions of ferulic acid.

Abraham in the rejection listed above, anticipated the compositions of claim 1 and 8 by teaching a composition containing ferulic acid with chlorogenic acid and caffeic acid (page 16, Table 1, Code C). This composition can be a supplement added to coffee (page 16, Table 1, Code C+D) and taken orally.

What Abraham does not teach is the use of his composition in hypertension. The broadest definition of hypertension includes both high systolic and high diastolic pressure as supported by (McGraw-Hill, definition of "hypertension"). Therefore one of ordinary skill in the art would recognize that the treatment of hypertension by this definition includes treating both the high systolic and high diastolic pressures.

While Abraham does not teach his compositions for use as a treatment of hypertension, Hsu does. Hsu teach that *Crataegus* is a common herb used to treat hypertension and it contains the active ingredients of chlorogenic acid and caffeic acid (Hsu, col 2, lines 58-61). Yokozawa et al. supports Hsu by teaching that caffeic acid and its derivatives are effective at treating hypertension (page 107, Table 1).

It would have been obvious to someone skilled in the art, knowing the teachings of Hsu, to treat hypertension using the composition of Abraham. Hsu provides the motivation by plainly stating that caffeic acid and chlorogenic acid are known treatments

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for hypertension. The reasonable expectation of success is provided by Hsu who states that *Crataegus* with its active ingredients of chlorogenic acid and caffeic acid are used to treat hypertension.

Claim 25 adds the limitation that the method uses a ferulic acid ester. While Abraham teaches the use of ferulic acid, he does not teach the use of the ester. However, one of ordinary skill in the art would recognize that an amount of ester ingested orally would be converted in at least part back to its corresponding acid via hydrolysis in the low pH environment of the digestive track. So it would be obvious to one of ordinary skill in the art to use the ester in place of the acid since in the digestive track the acid would be the predominate species that would eventually be transported into the body.

Claims 26-35 are drawn towards dosage regimes and schedules for the composition used by this method. While the references listed above do not specifically teach the limitations of the dosage regimes, composition ratios and schedules as seen in claims 26-35, one of ordinary skill in the art would recognize these limitations are result effective variables. Absent any teaching of criticality by the applicant concerning these limitations, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that dosage regimes, composition ratios and schedules are result effective variables which can be met as a matter of routine optimization (M.P.E.P. § 2144.05 II).

Also claim 11 limits that the composition is administered parenterally. One of ordinary skill in the art would recognize that any formulation that is safe for

administration orally can be reformulated to be administer parenterally, such as through an intravenous drip and is solely a matter of choice of the Experimenter (M.P.E.P. § 2144.04 IV B and 2144.06).

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 11-19 and 20-38 are not allowable.

Response to Applicant's Arguments-Obvious Type Double Patenting

Response to Applicants Amendment

In the response submitted by the applicant on 2/26/07 the Obvious Type Double Patenting rejection of claims 11-13 based on U.S. Patent Application # 11/209,672 is withdrawn in view of the abandonment of the above application.

In the response submitted by the applicant on 2/26/07, the Obvious Type Double Patenting rejection of claims 11-13 over U.S. Patent # 6,310,100 in view of Abraham as supported by Hsu and Yokazawa were considered but not found persuasive.

The Applicant argues that U.S. Patent # 6,310,100 fail to include caffeic acid and/or chlorogenic acid in a composition with ferulic acid. However the composition of U.S. Patent # 6, 310,100 does state that the composition is for the treatment of hypertension and comprises ferulic acid and pharmaceutical products. It is already known in the art as taught by Hsu and Yokazawa that caffeic and chlorogenic acids are known anti-hypertensives. M.P.E.P. § 2144.06 states

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"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more anti-hypertensives to the composition of U.S. Patent # 6,310,100 since they share the same purpose—to treat hypertension.

Furthermore the Applicant argues that synergistic results overcome the obviousness of such a method of treatment with this composition. However as mentioned above no evidence for synergism has been shown. Therefore the rejection stands and is repeated below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13 and new claims 20-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 in view of Abraham (Food and chemical toxicology, 1996) as supported by Hsu (U.S. Patent # 5,958,417) and Yokozawa et al. (Phytotherapy Research, 1995). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. The reference does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid, but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid as supported by Hsu (col 2, lines 58-60) and Yokozawa et al. (page 107, Table 1). Abraham discloses such compositions of isolated ferulic, chlorogenic, and caffeic acid that can be used to supplement food (Table 1, Code C and C+D). One of ordinary skill in the art would be motivated by U.S. Patent # 6,310,100 to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment for hypertension with such a composition as supported by Hsu and Yokozawa et al.

Also the provisional obvious type double patenting rejections over US 10/826,289 and US 09/922,694 also remain absent a terminal disclaimer or argument to the contrary. Those rejections are repeated here.

Claims 11-13 and 20-38 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-26 of copending Application No. 11/209,672, claims 2-6, 8, 11-16 and 20-29 of copending Application No. 10/826,289 and claims 1-19 of copending Application No. 09/922,694. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application are fully disclosed in the referenced copending applications and would be covered by any patent granted on either of those copending applications since the referenced copending applications and the instant application are claiming common subject matter, as follows: A treatment of hypertension using compositions of ferulic, chlorogenic, and caffeic acid.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending applications.

In summary no claims, as written, are allowed for this application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

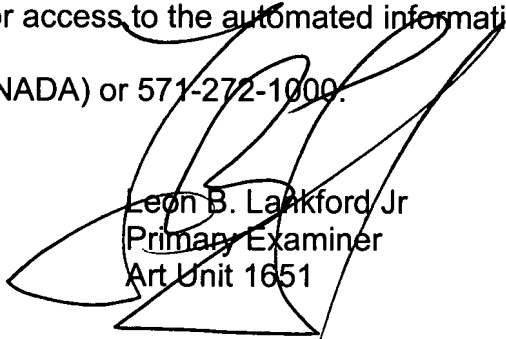
CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651



Leon B. Larkford Jr
Primary Examiner
Art Unit 1651